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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,407	12/12/2001	Edward A. Rhad	END-795	3685

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EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,407	RHAD ET AL.	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-8 and 13-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-8 and 13-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 5, 8, 13, 14, 15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals.

In regards to claims 5, 8, 13, 14, 15 and 18, Kellogg, Jr. discloses a biopsy device (Figure 1) including an elongated substantially tubular needle having a distal end (12), a proximal end, a longitudinal axis there between, a cutter lumen (Col. 2, lines 43 - 44), a non-metallic liner (20) extending along a portion of the cutter lumen; a vacuum lumen (14), a side port (10b) for receiving a tissue sample (Col. 3, lines 55 – 56); a sharpened distal tip for insertion within tissue (Col. 3, lines 45 - 49), the sharpened distal tip attached to the distal end of the needle and a cutter (24) movable within the cutter lumen (Col. 2, lines 62 – 64). However, Kellogg, Jr. fails to disclose the needle being non-metallic and the distal tip having a cavity in which an artifact creating material is disposed. Van Vaals discloses a non-metallic biopsy needle (Col. 6, lines 55 – 60) including a distal tip (6; Figure 2) having a cavity in which an artifact creating material is disposed (Figure 3; Col. 6, line 61 – Col. 7, line 34). Van Vaals discloses the artifact creating material as being selected from the group of gadolinium, titanium, aluminum, copper, brass and bronze (Col. 7, lines 1 – 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy needle as disclosed by Kellogg, Jr. to be non-metallic and to include a distal tip having a

cavity in which an artifact creating material is disposed as taught by Van Vaals in order to track the needle within the body of the patient so as to guide the needle safely through the body without damaging the tissue and to guide the needle to the desired position (Col. 2, lines 41 – 50).

3. Claims 6 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals as applied to claims 5 and 15 above, and further in view of U.S. Patent No. 6,272,370 to Gillies et al.

In reference to claims 6 and 16, Kellogg, Jr. in view of Van Vaals discloses an MRI compatible device comprising a needle including a non-metallic material including plastic or a ceramic material (Col. 6, lines 55 – 60). Kellogg, Jr. in view of Van Vaals fail to disclose the non-metallic material comprising a thermoplastic. However, Gillies et al. discloses an MRI compatible device formed of a non-metallic material including a thermoplastic (Col. 24, lines 17 – 19). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to form the needle as disclosed by Kellogg, Jr. in view of Van Vaals of a thermoplastic as taught by Gilles et al. or any MRI compatible material as desired.

4. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No 3,606,878 to Kellogg, Jr. in view of U.S. Patent No. 6,430,429 to Van Vaals as applied to claims 5 and 15 above, and further in view of U.S. Patent No. 5,782,764 to Werne.

In reference to claims 7 and 17, Kellogg, Jr. in view of Van Vaals discloses an MRI compatible device comprising a needle including a non-metallic material including plastic or a ceramic material (Col. 6, lines 55 – 60). Kellogg, Jr. in view of Van Vaals fail to disclose the non-metallic material comprising a glass fiber reinforced polymer resin. However, Werne discloses an

MRI compatible device including a needle comprising a glass fiber reinforced polymer resin (Col. 8, lines 36 – 65). The selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, it would have been obvious to one having ordinary skill in the art to form the needle as disclosed by Kellogg, Jr. in view of Van Vaals of a glass fiber reinforced polymer resin as taught by Werne or any MRI compatible material as desired.

Response to Arguments

5. Applicant's arguments filed 10/13/05 have been fully considered but they are not persuasive. Applicant asserts that the Examiner has not shown the required motivation in the prior art to modify Kellogg, Jr. by the teaching of Van Vaals and that the combination suggested by the Examiner is based on improper hindsight reliance of Applicant's invention. However the Examiner disagrees. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the present case, Kellogg, Jr. teaches a standard biopsy needle. Van Vaals teaches an improved biopsy needle (Col. 6, lines 55 – 57) being formed of a non-metallic material and having a cavity in the distal tip in which an artifact inducing material is placed (Col. 6, line 64). Van Vaals teaches that such a biopsy needle is beneficial because it allows introduction of the needle into a patient while being guided by magnetic resonance imaging. The Examiner has used such a teaching as the motivation to modify the needle as disclosed by Kellogg, Jr. with the teachings of Van Vaals. The

Examiner maintains that the motivation to modify the prior art to arrive at the present invention has come from the references themselves and renders the claims unpatentable under 35 U.S.C. 103(a) over Kellogg, Jr. in view of Van Vaals.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JML/

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SUPERVISORY PATENT EXAMINER
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